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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/770,562	01/26/01	CURATOLO W	PC9674AJTJ

EXAMINER	
EUROPA R	
ART UNIT	**PAPER NUMBER**
1615	5

HM12/0911

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DATE MAILED: 09/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/770,562	CURATOLO ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-38 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 & 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Examiner acknowledges receipt of preliminary amendment filed 5/7/01.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 7, 11, 15, 19 and 27 recite the abbreviation HPMCAS which according to Japanese unexamined patent application (Kokai) No. 57-176907 is a trade name by Shin-Etsu Kagaku (see page 2 of translation, line 7). Thus claims 1, 7, 11, 15, 19 and 27 contain the trademark/trade name HPMCAS. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe hydroxypropyl methyl cellulose acetate succinate and, accordingly, the identification/description is indefinite.

Where the HPMCAS is no longer a trade-secrete, the claims are indefinite for reciting abbreviation. Applicants may overcome this rejection reciting the description for the term.

Claims 6, 7 and 22 recite "MFD". This term is indefinite. Applicants may overcome this rejection by defining what "MFD" is. Applicants may in the least initially recite the definition for the term with the abbreviation/term enclosed within parenthesis. Applicants may subsequently use the term/abbreviation (MFD) after the initial definition of the term in a claim.

Claim 15 recites the abbreviation/term "AUC". This term is indefinite. An initial description of the term in the claim may be sufficient to over the rejection. Applicants may subsequently use the term/abbreviation (AUC) after the initial definition of the term in a claim.

Claim 33 recites the abbreviation/term "CRH." This term is indefinite. An initial description of the term in the claim may be sufficient to over the rejection. Applicants may subsequently use the term/abbreviation (CRH) after the initial definition of the term in a claim.

The phrase "in a use environment" in line 3 of claim 1 is confusing. What is "in a use environment"?

3. Claims 28-38 recite the limitation "said compound" in lines 1 and 2 of the claims. There is insufficient antecedent basis for this limitation in the claim.

4. Claims 2, 8, 14 and 18 are confusing and are not examined on the merits.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4, 5, 7, 10, 11, 13, 15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by JP (Kokai) No. 57-176907.

The claims read on solid compositions comprising a sparingly water-soluble drug and hydroxypropyl methyl cellulose acetate succinate. The solid composition is prepared by spray drying.

The prior art discloses a solid preparation comprising 4-(cis-p-methan-8-yloxy)benzanilide (poor water-soluble drug) and hydroxypropyl methyl cellulose acetate succinate. The preparation is spray dried or vacuum dried. See pages 2-7 of translation. However, the process of preparing a composition is not critical in a composition claim. What is required is for the prior art to teach the composition and the process of making the composition does not distinguish over the prior art. Thus, the teachings of the prior art read on the claims.

7. Claims 1, 4, 5, 7, 10, 11, 13, 15, 17 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by JP (Kokai) No. 2-15027.

The prior art teaches a solid preparation comprising probucol (poor water-soluble drug) and hydroxypropyl methyl cellulose acetate succinate polymer and the mean particle diameter is not more than 10 μm (see pages2-8 of translation). The process of preparing a composition is not critical in a composition claim. A mean particle diameter of 10 μm is less that 100 μm. It is only required that the prior art to teach the composition and the process of making the composition does not distinguish over the prior art. Thus, the teachings of the prior art read on the claims.

8. Claims 1, 7, 11, 15, 36 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamichi et al. (US 5,456,923).

Nakamichi teaches a solid composition comprising a drug and hydroxypropyl methyl cellulose acetate succinate (abstract, column1, lines 59-63, column 2, lines 43-47 and column 6,

lines 11-19). Some of the drugs applicable in the invention are theophylline, phenytoin and enalapril (column 4, lines 26-28, column 5, lines 14-16 and lines 47-49). The process of preparing a composition is not critical in a composition claim. What is required is for the prior art to teach the composition and the process of making the composition does not distinguish over the prior art. Thus, the teachings of the prior art read on the claims.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 19-21, 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP (Kokai) No. 57-176907.

The teachings of the prior art are discussed above. The JP (Kokai) No. 57-176907 reference is silent on the size of the particle. However, the process of the prior art would yield particles that one having ordinary skill in the art would determine. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of JP (Kokai) No. 57-176907. One having ordinary skill in the art would have been motivated to prepare the composition of JP (Kokai) No. 57-176907. One having ordinary skill in the art would know routine experimental process of measuring particle sizes. Applicants provided no indication of the concentration of drug or solvent that would yield particle size of less than 100 μm in diameter. In the absence of a showing, the particle size does not distinguish the invention over the prior art.

11. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP (Kokai) No. 2-15027.

The teachings of JP (Kokai) No. 2-15027 are discussed above. However, the prior art is silent on the ratio drug to hydroxypropyl methyl cellulose acetate succinate. Although, the prior art is silent, it is obvious that the composition comprises a certain amount of drug and a certain amount of the polymer. The prior art teaches 10 parts of the drug probucol to 13 part of polymer that is not hydroxypropyl methyl cellulose acetate succinate (examples 1-2). The ratio appears to be an optimization of the composition. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of JP (Kokai) No. 2-15027. One having ordinary skill in the art would have been motivated to prepare the composition of the prior art and to optimize the ratio of the drug to the polymer as desired for the composition.

12. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification and in the claims.

13. Suggestion that may expedite prosecution:

Applicants are invited to correct the issues under 35 U.S.C. 112, second paragraph; amend the generic claims to more clearly reflect the invention keeping in mind that how a composition is made is not critical, keeping in mind that the prior art teaches particles size of less than 100 μm and ratio of drug to polymer that lies within the range claimed.

The prior art appears not to teach compositions comprising the drugs recited in claims 29,30, 32, 34 and 35.

It is noted that applicants have not submitted the information disclosure statement filed in the parent case.

Applicants' representative is also invited to telephone the examiner if the examiner can be of assistance in clarifying some of the issues raised.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
September 7, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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